PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F

A2

(11) International Publication Number: **WO 98/53759**

(43) International Publication Date: 3 December 1998 (03.12.98)

(21) International Application Number: PCT/US98/11448

(22) International Filing Date: 28 May 1998 (28.05.98)

(30) Priority Data:
60/047,994 28 May 1997 (28.05.97) US

(71)(72) Applicant and Inventor: YADAV, Jay, S. [US/US]; 735 Aran Drive, Roswell, GA 30076 (US).

(74) Agents: DIPPERT, William, H. et al.; Cowan, Liebowitz & Latman, P.C., 1133 Avenue of the Americas, New York, NY 10036–6799 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: CAROTID STENT

(57) Abstract

A stent for cardiovascular application wherein a substantially cylindrical tubular member tapers from its proximal end to its distal end.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

CAROTID STENT

FIELD OF THE INVENTION

This invention relates to stents useful in cardiovascular applications. More particularly, this invention relates to a tapered stent useful in tapered arteries including the carotid arteries.

BACKGROUND OF THE INVENTION

Angioplasty and stenting have been widely applied to the coronary arteries as well as to the peripheral circulation. Recently the feasibility of stenting the carotid arteries, including the internal, external and common carotid arteries, has been shown. None of the existing stents is ideally suited for stenting the common carotid bifurcation or the proximal internal carotid artery. This is a significant problem since these are the most frequent sites for cerebrovascular atherosclerotic disease.

Current stents, whether balloon-expandable or self-expanding, are straight tubes which have two major shortcomings when used in carotid applications. First, they do not fit the fairly rapid taper of the proximal internal carotid artery. And second, they tend to compromise the flow to the external carotid artery.

OBJECTS OF THE INVENTION

It is an object of the invention to provide a novel, tapered stent.

It is also an object of the invention to provide a stent especially useful in carotid arteries.

It is a further object of the invention to provide a stent having a lateral opening to facilitate blood flow to the external carotid artery.

These and other objects of the invention will become more apparent from the discussion below.

SUMMARY OF THE INVENTION

According to the invention a substantially cylindrical stent is tapered from one end to the other. The taper can be linear or non-linear, and the stent can be balloon-expandable or self-expanding. The diameters at the ends of the stent and the degree of tapering can be varied to adapt to a wide range of artery sizes and geometries. When the stent tapers from the proximal to the distal end, it fits the smaller distal internal carotid artery as well as the larger carotid bulb without overdistending the distal artery or being undersized in the carotid bulb.

Preferably the stent of the invention is a self-expanding stent made from a shape-memory metallic alloy such as nitinol or superelastic nitinol. However, other metallic and non-metallic alloys, including stainless steel, can be used as well.

The stent can also be made with a small circular opening in the proximal portion of the stent allowing blood flow to the external carotid artery. Devices can also be passed through this opening into the external carotid for treatment purposes. Radiopaque markers placed around the circumference of this opening allow proper positioning of the opening at the origin of the external carotid artery.

The stent will be delivered inside a sheath which will be withdrawn, allowing for release and expansion of the stent. The stent will preferably be sufficiently radiopaque to be easily visible under fluoroscopy; however, optimally radiopaque markers could also be placed at the ends of the stent to further aid placement.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic view of a stent according to the invention within a delivery sheath;

Figs. 2 and 3 are each an oblique view of an embodiment of the stent according to the invention;

Figs. 4 and 5 are each a cross-sectional schematic of an embodiment of the stent of the invention;

Fig. 6 is a partly cross-sectional view of a carotid artery with plaque; and

Fig. 7 is a partly cross-sectional view of the carotid artery in Fig. 4 with a stent according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

The invention can perhaps be better appreciated by referring to the drawings. In Fig. 1 a stent 1 is positioned circumferentially around a delivery catheter 2 within a sheath 4. Stent 1 is held in a constrained state by reusable fasteners 6 to the surface of delivery catheter 2. Catheter 2, stent 1, and sheath 4 track along guidewire 8 until stent 1 reaches a desired location, at which time sheath 4 is moved proximally and then stent 1 is released from delivery catheter 2.

Various delivery systems for self-expanding or balloon-expandable stents are known and would be applicable here. See, for example, U.S. Patents Nos. 4,886,062, 4,913,141, 5,507,768, 5,147,370, 5,534,007, 5,571,135, 5,632,760, 5,643,278, and 5,669,932, each of which is incorporated herein by reference, especially for the teaching of stent delivery systems.

An expanded stent 1 is shown in Figs. 2 and 3, where it can be seen that stent 1 tapers from proximal end 12 to distal end 14. The taper can be linear, gradual, or irregular, dependent upon the intended application. Preferably stent 1 will have an opening 16 approximately 20

to 40% of the distance between the proximal and distal ends of the stent. Opening 18 may have one or more, preferably 3 or 4, equally spaced radiopaque markers to assist in positioning. Similarly, each of stent ends 12 and 14 may optimally have one or more, preferably 2 to 4, equally spaced radiopaque markers 20.

As mentioned earlier, the diameters of the ends 12,14 of the stent and the lengths of the stent will vary greatly. In a preferred embodiment for carotid application, it is envisioned that stent 1 will have a diameter of from about 9 to 11 mm at its proximal end and a diameter of from about 6 to 8 mm at its distal end, with a substantially linear taper. Opening 16 will be circular or oval, with an effective diameter of from about 2 to 4 mm.

Additional, preferred embodiments of the tapered stent of the invention in expanded form can be seen in schematic form in Figs. 4 and 5. A stent 22 comprises a substantially tubular or cylindrical proximal section 24, a linearly tapered intermediate section 26, and a substantially cylindrical distal section 28. Here, proximal section 24 has a length of approximately 10 mm and a diameter of approximately 10 mm, intermediate section 26 has a length of approximately 15 mm and a distal diameter of approximately 6 mm, and distal section 28 has a diameter of approximately 6 mm and a length of approximately 15 mm. In Fig. 5 a stent 30 comprises a proximal section 32 and a distal section 34, where proximal section 32 has an increasingly tapered, somewhat parabolic shape where the diameter changes from approximately 10 mm to approximately 6 mm and distal section 34 has a substantially constant diameter of approximately 6 mm. The respective lengths of proximal and distal sections 32 and 34 are from about 20 to 30 mm for section 32 and from about 10 to 20 mm for section 34, the total length of stent 30 being about 40 mm.

Fig. 6 represents a cross-sectional view of a carotid artery 42, wherein plaque 44 obstructs blood flow. As can be

seen in Fig. 5, a stent 46 has been positioned in the stent after a procedure such as angioplasty or atherectomy, where the tapered ratio of stent 46 facilitates comfortable placement. The opening 48 facilitates blood flow to the external carotid artery.

The stent of the invention preferably comprises a self-expanding structure, although a balloon expandable structure could work as well. Self-expanding and/or balloon expandable lattice-work structures are well known. See, for example, U.S. Patents Nos. 5,527,354, 5,545,211, 5,540,712, 5,545,210, 5,549,635, 5,653,727, 5,562,641, 5,562,725, 5,569,295, 5,571,166, 5,591,197, 5,591,230, 5,575,816, 5,575,818, 5,603,721, and 5,628,788, each of which is incorporated herein by reference, especially for the teachings of the structures and materials useful in self-expanding and balloon expandable stents.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

I CLAIM:

1. A stent for cardiovascular application wherein a substantially cylindrical tubular member tapers from its proximal end to its distal end.

2. The stent of Claim 1, which has a lateral opening for blood flow.

3. The stent of Claim 2, wherein the lateral opening is located approximately 20 to 40 % of the distance from the proximal end to the distal end.

4. The stent of Claim 1 which is self-expanding.

5. The stent of Claim 1, wherein the tubular member comprises a distal section that is substantially cylindrical, and intermediate section that is substantially linearly tapered, and a distal section that is substantially cylindrical.

6. The stent of Claim 5, wherein the diameter of the distal end is about 10 mm and the diameter of the proximal end of about 6 mm.

7. The stent of Claim 5, wherein the proximal section is about 10 mm in length, the intermediate section is about 15 mm in length, and the distal section is about 15 mm in length.

8. The stent of Claim 1, wherein the stent comprises a proximal section having an increasingly tapered shape and a distal section having a substantially cylindrical shape.

9. The stent of Claim 8, wherein the diameter of the proximal end is about 10 mm and the diameter of the distal end is about 6 mm.

10. The stent of claim 8, wherein the length of the proximal section is from about 20 to 30 mm and the length of the distal section is from about 10 to 20 mm.

11. A method of treating a carotid stenosis which comprises the steps of

engaging plaque in a carotid artery to remove the plaque or to open a space within the plaque,

advancing a guidewire into the carotid artery,

advancing a delivery catheter comprising a stent of Claim 1 in a collapsed or constrained configuration over the guidewire to a point adjacent the stenosis, and

releasing the stent from the delivery catheter.

12. The method of Claim 11, wherein the stent has a lateral opening and the lateral opening is positioned to facilitate blood flow to an external carotid artery.

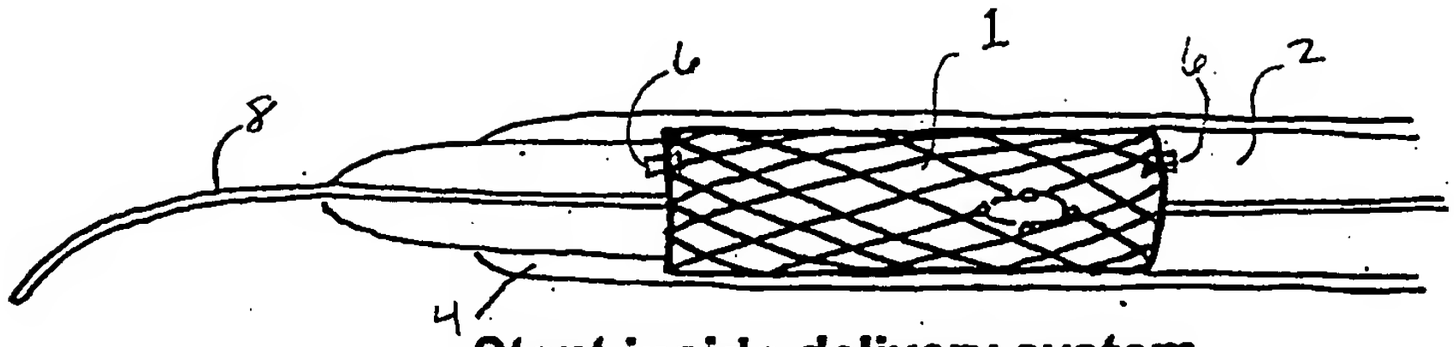
13. A method of treating a carotid stenosis which comprises the steps of

advancing a guidewire into a carotid artery,

advancing a delivery catheter comprising a stent of claim in a collapsed or constrained configuration over the guidewire to a point adjacent the stenosis, and

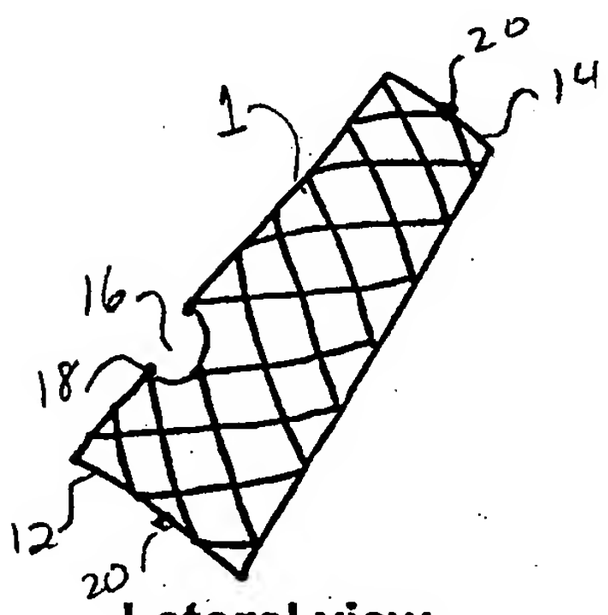
releasing the stent from the delivery catheter.

14. The method of Claim 13, wherein the stent has a lateral opening and the lateral opening is positioned to facilitate blood flow to an external carotid artery.



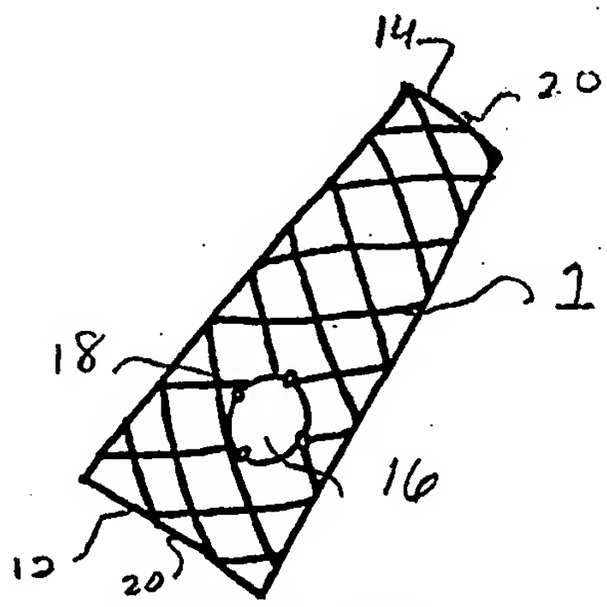
Stent inside delivery system

Fig. 1



Lateral view

Fig. 2



Frontal view

Fig. 3

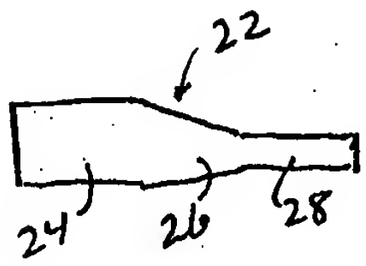


Fig. 4

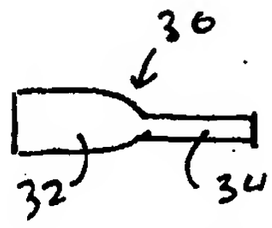
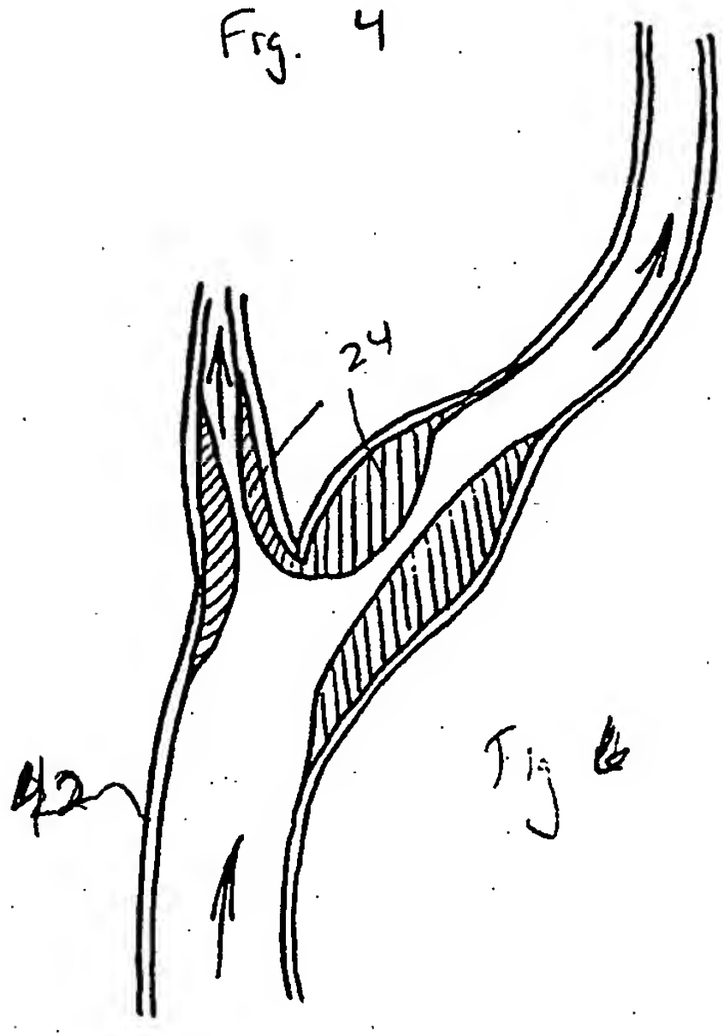
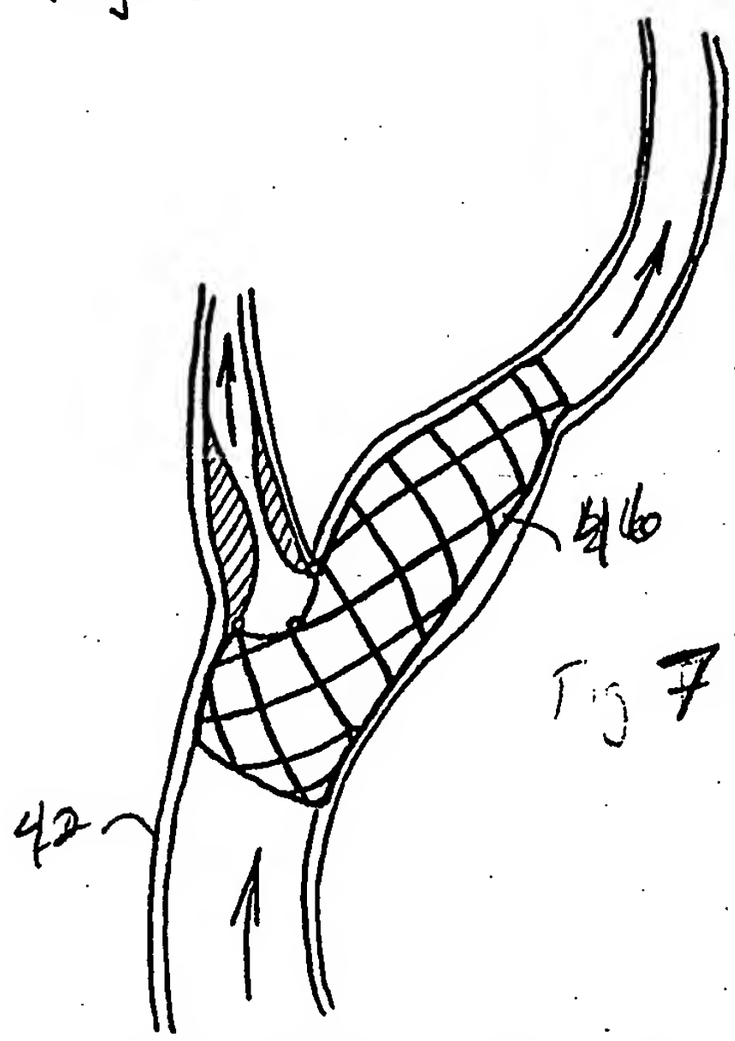


Fig. 5



Carotid bifurcation with plaque

Fig 6



Carotid bifurcation with stent

Fig 7